

## REMARKS

### A. Status of the Claims/Amendments

Claims 1-3, 9-15, 20-21, 24, 30-32 and 35-45 are pending and currently under examination.

Further, the specification has been amended consistent with Applicant's hereinbelow request that the status of the present application be changed from "continuation" to "division" of the parent.

### B. Rejections On the Basis of Alleged Anticipation

The Action rejects claims 15, 20-21, 30, 32, 39, 42-44 and 45 under 35 U.S.C. §102(a) as anticipated by Gong *et al.* (Asian Pacific Bio Tech News).

In response, Applicants would note that in connection with its response dated February 20, 2008, a "swearing back" declaration under Rule 131 was provided. That declaration was found to be sufficient to remove a reference (the Bryan patent) having a priority of March, 1998. In view of the current record, and particularly in view of the previous Rule 131 declaration, the Action has failed to demonstrate that the Gong *et al.* Asian Pacific reference is available as prior art under 35 U.S.C. §102(a). The Examiner is thus requested to withdraw this rejection.

### C. Rejections On the Basis of Alleged Obviousness

#### 1. Rejections that rely upon the Hua thesis, document C89

Applicants note the entry of 8 separate obviousness rejections on pages 5 through 16 of the subject Action, involving various combinations of references rejecting each of the pending claims. Each of these eight rejections relies principally on the Hua thesis, IDS document C89. Applicants respectfully traverse this rejection on the basis that the Hua thesis is not available as prior art under either 102(a) or 102(b).

Firstly, the Hua thesis has not been shown by the Action to be sufficiently “publicly accessible” to constitute a printed publication. As noted by the Federal Circuit recently in *Cordis Corp. v. Boston Scientific Corp.*, 90 USPQ2d 1401, 1411-12, \_\_\_ F.3d \_\_\_, \_\_\_ (Fed. Cir. 2009), a document is publicly accessible only if it “has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.” *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981) (quoting *I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743 (S.D.N.Y.1966)). In general, “[a]ccessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to.” *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988). Moreover, many of the Federal Circuit cases in this area have concerned publications available in libraries, and the question has been whether the publication has been sufficiently indexed to be publicly accessible. See, e.g., *In re Cronyn*, 890 F.2d 1158, 1161 (Fed. Cir. 1989); *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986); *In re Wyer*, 655 F.2d at 226. Other cases have involved widespread distribution so that the public could easily obtain copies of the publication. See, e.g., *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1350-51 (Fed. Cir. 2008). The Action fails to provide evidence of public accessibility that would be cognizable under the foregoing caselaw.

While it is not believed that the Action has met its burden in making out a *prima facie* case, Applicants further note the enclosed declaration of Dr. Zihyuan Gong, further in support of Applicant’s contention that the Hua reference was not “publicly available” under the foregoing caselaw. In the enclosed declaration, Dr. Gong provides the following facts:

In paragraph 3 of the declaration, Dr. Gong first observes that the authors of documents C89 and C90 were students in his laboratory enrolled in the Undergraduate Honors Program at the National University of Singapore. He states that the Undergraduate Honors Program is one to which undergraduate students may apply after they have completed 3 years of study, and consists of approximately 70% course work and 30% research. The first semester of the program is said to consist exclusively of course work and in the second semester, in addition to some further course work, the students are required to conduct research and write a lengthy report on their research. Documents C89 and C90 are stated to be examples of such reports. Notably, Dr. Gong confirms that both students worked in his laboratory under his direction and control.

In paragraph 4, Dr. Gong continues by noting that the manner in which such thesis reports are handled within his department, the Department of Biological Sciences, is as follows, which he confirmed with the departmental secretary: Once the report is completed, it is given to the department secretary, who then sends the report to a departmental examiner, who conducts a review (*i.e.*, grades the thesis). The departmental examiner is then required to return the thesis to the department. The department generally, but does not always, retain a copy of such reports in the departmental files. There is no card cataloguing of such reports in the department. Copies of some of these reports were at one time kept in a departmental reading room in the 1998 time frame. However, that reading room is no longer in existence, and when it was, that room was for internal use only. It is unknown whether copies of documents C89 or C90 were ever retained in the departmental reading room.

Dr. Gong concludes by noting again that these students worked under his direction and control on a project that he (Dr. Gong) designed and implemented, and that a copy of each of documents C89 and C90 was retained in his personal files.

Lastly, in paragraph 5, Dr. Gong states that he visited the National University of Singapore library in 2009 and confirmed that neither document C89 nor C90 was listed in the library card catalogue, and that he was unable to otherwise find either document in the library.

Thus, not only does the Action fail to make out a *prima facie* case of public availability, the facts provided by Dr. Gong and recited above compel the conclusion that the Hua document was *not* publicly available.

If the Action is instead relying on the Hua reference under some other theory, such as 102(a), 102(f) or 102(g), we would note at the very least that the enclosed Gong declaration confirms that the work described in the Hua document was conducted under Dr. Gong's direction and control. See *In re Katz*, 687 F.2d 450 (CCPA 1982). If the rejection over Hua is maintained, the Examiner is requested to precisely state the basis for alleging that the Hua document is considered to be prior art.

Applicants have reviewed the remaining references and do not find it necessary at this time to address them as clearly they do not, by themselves, provide a *prima facie* basis for an obviousness rejections. Nonetheless, should an appeal be necessary, Applicants reserve the right to address these references in its appeal.

2. *Rejection of claims over Highashijima et al. in view of Yanong et al.*

The Action next rejects claims 1, 36-37, 39-40, 42-44 and 45 as obvious over the combination of Higashijima *et al.* ("Higashijima") in view of Yanong *et al.* ("Yanong").

Firstly, with respect to claim 1 (which depends from claim 43) and claims depending therefrom, we would note that this claim requires that the transgenic fish be capable of expressing the fluorescent gene "at a level sufficient such that said transgenic fish *fluoresces upon exposure to sunlight*, wherein said transgenic fish are the offspring of an embryo line

visually exhibiting expression of the fluorescent protein in essentially all muscle fibers in their trunk and further *wherein transgenic founders of said line fluoresce upon exposure to sunlight.*"

The Higashijima reference was previously relied upon as to this claim. In Applicant's response filed January 9, 2008, Applicants provided the following argument and evidence, resulting in the withdrawal of art rejections relying upon Higashijima:

We know that the fish disclosed by Higashijima fail to meet this limitation based on an email exchange between the present inventor, Dr. Gong, and an author of the Higashijima article, Dr. Hitoshi Okamoto (copy enclosed). In this email exchange, there is a first email from Dr. Gong to Dr. Okamoto, dated November 30, 2007, wherein Dr. Gong states to Dr. Okamoto as follows:

I understand that you made GFP transgenic zebrafish lines under the alpha-actin promoter and GFP is expressed in zebrafish muscle. This work was published in 1997 by Higashijima et al. Dev. Biol. 192:289-299. We made GFP and RFP transgenic [sic] zebrafish lines under the myl2 promoter and they displayed strong visible fluorescent colors in adult fish even under the normal daylight. I recall that when you visited our aquarium [sic] several years ago, *you mentioned that this visible fluorescent color was not observed in your adult fish of alpha-actin:GFP transgenic lines. You just confirmed the same information over the phone.*

(emphasis ours). In a responsive email dated December 10, 2007, Dr. Hitoshi confirmed that the actin promoter fish described in the Higashijima article did not fluoresce in sunlight.

Turning to Chalfie, this reference appears to be totally devoid of relevance to any of the foregoing issues as it simply to the fluorescent protein genes and their use. We note that Chalfie is apparently merely being cited for the proposition that fluorescent protein genes were known. Action, para. bridging pages 13-14.

Based on the foregoing, it is evident on this record that the combination of Higashijima and Bryan do not meet the limitations of the claims, and there is no other teaching of record that would teach or suggest that the production of transgenic fish that fluoresce in sunlight is desirable or even possible.

In response to this evidence, the Examiner stated in the subsequent Action dated June 10, 2008, that the various art rejections over Highashijima were withdrawn, with the Examiner

stating that “[a]dditionally, Applicants have submitted evidence to indicate that transgenic fish disclosed by Higashijima et al do not fluoresce under sunlight (see the email as appendix and applicants argument).” Action, page 17.

In light of the foregoing and in view of the lack of comments regarding the previous evidence, argument and withdrawal of rejection, we assume that claim 1, and dependent claims to the extent they depend from claim 1, were inadvertently included in this rejection. If Applicants are in error, the Examiner is requested to explain the relevance of these references to claim 1.

Independent claim 43 does not include the “sunlight” limitation. However, we contend that the Yanong reference is of little relevance to the rejection with respect to claim 43 (and claims depending therefrom). From our review of Yanong, it appears that coloration is primarily discussed in the context of good fish nutrition. Indeed, it appears that the examiner is referring to the section entitled “Nutrition” and more particularly to the paragraph at the bottom of page 227 of the Nutrition section. There, Yanong discloses that in order to maintain their coloration, ornamental fish must be provided the appropriate types of food and nutrition. Indeed, other excerpts from Yanong, in particular, the paragraph bridging pages 223/224, teach that fish that have been exposed to color enhancement techniques “should not be chosen for breeding purposes.” Thus, we see no basis whatsoever for combining Yanong with Higashijima, which teaches at best that coloration is enhanced through good nutrition and appropriate diet.

Moreover, to the extent that Yanong discusses coloration at all, it is evident that Yanong is referring to coloration that is visible to the eye under normal lighting conditions. However, we have already established on the record that the fish of Higashijima are not colorful under normal light (see above). Thus, one of skill, knowing that the fish of Higashijima are NOT colorful

under the lighting conditions contemplated by Yanong, would clearly NOT find such fish to be of commercial interest and would disregard them.

For the foregoing reasons, the Examiner is requested to reconsider and withdraw the rejection over Higashijima in view of Yanong.

**D. Non Statutory Obviousness-Type Double Patenting**

*1. Provisional rejection over USSN 10/749,032*

The Action lastly provisionally rejects claims 1-3, 9-15, 20-21, 24, 30-32 and 35-45 over claims 42-46, 53-55, 58-60, 63-65 and 68-81 of copending Application No. 11/749,032 on the basis of alleged non-statutory obviousness-type double patenting.

Applicants note that a provisional double-patenting rejection is not a final rejection that blocks the prosecution of all of the conflicting applications. If a provisional double-patenting rejection is the only rejection remaining in an application, the Examiner should withdraw the rejection and permit the application to issue as a patent. MPEP § 804(I)(B). After one application issues as a patent, the provisional double-patenting rejection in the remaining application is converted to an actual double patenting rejection. *Id.* Thus, either the present application or the copending application must issue as a patent before an actual double patenting rejection may be raised against the remaining application.

*2. Rejection over US 7,135,613*

Lastly, the Action rejects claims 1-3, 9-16, 19-21, 24, 30-32 and 35-45 over claims 1-7 of U.S. Patent 7,135,613 on the basis of alleged non-statutory obviousness-type double patenting.

In response to double patenting over U.S. Patent 7,135,613, Applicants respectfully traverse. Applicants again note that during the prosecution of USSN 09/913,898, Applicants attempted to introduce claims consistent with the claims pending in the present application. See

Applicant's Amendment dated May 9, 2003. In response to this attempted amendment, the Examiner refused entry of the amendment: "The amendment filed on May 12, 2003 ... presenting only claims drawn to a new invention is **non-responsive** (MPEP §821.03) (underline added)," taking the position that such claims were found not to be drawn to the invention elected in that case, which later became the '613 patent. See Restriction Requirement mailed 12/18/03 and, again, the Restriction Requirement dated 7/30/03. Thus, the PTO has already decided that the present claims are patentably distinct.

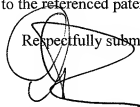
The Action responds to the foregoing argument by implicitly recognizing that the respective inventions are patentably distinct, stating that Applicant's argument would be persuasive if the status of the present application were changed to "divisional." Applicants hereby request that the status of the present application be changed to divisional, and have proceeded to amend the specification in a manner consistent with this request. Applicants therefore understand that by making this amendment, the present claims now have the full benefits and protections of 35 U.S.C. §121. See *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, App. Nos 09-1020, -1096, \_\_\_ F.3d, \_\_\_ (Fed. Cir. 2009); *Pfizer, Inc. v. Teva Pharmaceutical USA, Inc.*, 518 F.3d 1353, 1358-62 (Fed. Cir. 2008).



### CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

The Examiner is invited to contact the undersigned attorney at (512) 536-3055 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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